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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,276	12/06/2001	Roy L. Barrus	S-8492 (1502-71 CIP II)	4052
55825 7590 01/04/2007 CARTER, DELUCA, FARRELL & SCHMIDT, LLP 445 BROAD HOLLOW ROAD SUITE 225 MELVILLE, NY 11704			EXAMINER WILLIAMS, CATHERINE SERKE	
			ART UNIT 3763	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/016,276

Applicant(s)

BARRUS ET AL.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8, 11-14, 33 and 35-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33 and 35-37 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 11-14 and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7-31-06 10/5/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3,5,7,38 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al (USPN 6,824,530).

Wagner discloses a device including a ninety degree angle needle (16) having a distal portion and a proximal portion. See figures 3 and 14-17. The device also includes a shield (see figure 17) having at least one elongated part (46), a proximal end mounted with the proximal end of the needle, a distal end mounted with a planar contact surface (56) and a hub with appendages (44). See also figures 14-17. The shield is extensible between a retracted position (figure 14) and an extended position (figure 17) via fixed positioning of the planar contact surface relative to movement of the shield. Regarding the claim limitation of “via fixed positioning of the planar contact surface relative to movement of the shield”, see the disclosure of the operation of the needle 4:60-5:16. The device also includes a distal end of the foldable legs (46) of the shield being hingedly attached to the circular portion (56) of the planar contact shield (56) via linear bearing (54). The needle and the shield segments are moveable in relation to the linear bearing. See figures 14-17.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by Wagner in view of FR2803529. Wagner meets the claim limitations as described above but fails to teach the appendage having at least one opening. However, FR2803529 discloses such an appendage with at least one opening.

At the time of the invention, it would have been obvious to incorporate the at least one opening as taught by FR2803529 into the invention of Wagner. The motivation for the incorporation would have been commonly known by one skilled in the art. The motivation would have been to provide an attachment point for tape or another attachment mechanism to enhance the adhesion of the device to the patient during use.

Claims 8 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner in view of Bell (US Pat# 5,997,504). Wagner meets the claim limitations as described above but fails to teach the planar contact surface having a pad, an anchor part, and texturing.

Bell discloses a safety shield apparatus including needle (16,18) and a shield (see figures 12A-12C). The shield includes at least one elongated part with a proximal end mounted with the proximal portion of the needle and a distal end mounted with a planar contact surface (120). The planar contact surface also has a linear bearing (131) that slidably facilitates movement of

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the needle relative to the shield. See figure 11. The shield is shown being extensible between a retracted position and an extended position via relative movement between the surface (120) and the proximal portion of the shield (see figures 12A-12C). The device further includes a needle hub (104), an appendage wing (44), segment (28) and channel (inside 28). A latch (112) is shown in figure 12D with an arm having a plurality of surfaces including an arcuate surface. The needle is angularly displaced approximately 90 degrees (see figure 4A). **The planar contact surface includes an anchor/pad (122) which is an adhesive pad (texturing due to the adhesive).** The distal end of the shield is hingedly attached to the contact surface (see figures 12A and 12B).

At the time of the invention, it would have been obvious to incorporate the teaching of the pad/anchor of Bell on to the planar contact surface of Wagner. The devices are analogous in the art of needle shields and therefore a combination is proper. Additionally, the anchor/pad of Bell facilitates an efficient and comfortable securing of the device to the patient. See paragraph 37 of Bell. Additionally, one skilled in the art would recognize the advantage of having a comfortable and secure attachment mechanism to the patient. The disclosure of Wagner states that in the operation of the device one has to hold down the planar contact surface while pulling up the needle hub. See step 3 at 5:1-9. One skilled in the art would recognize that having an adhesive pad/anchor on the device of Wagner would eliminate the need for holding down the planar contact surface; thus, making the device of Wagner easier to use.

Claims 11-13 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (USPN 6,824,530) in view of Kuracina et al (US Pat# 5,879,337).

Wagner meets the claim limitations as described above but fails to include the linear bearing that slidably engages the needle having a latch. However, Kuracina discloses such a linear bearing having latch. The device includes a latch (41) engageable with the needle where the latch includes an arm (see figures 30-31) for maintaining the shield in the extended position (see figure 31) and a plurality of surfaces (the distal end and side surface of the interior of the latch arm (41) configured to maintain the shield in the extended position (see figure 31).

At the time of the invention, it would have been obvious by one skilled in the art to modify the distal end interior of the needle shield (54) of Wagner (the embodiment of figure 14-17) by incorporating the latch (41) as taught by Kuracina (figures 30-31). Both devices are analogous in the art of needle shields; therefore, a combination is proper. Additionally, as taught by Kuracina, the latch (41) works to automatically entrap or capture the sharpened tip of the needle after use (see 3:26-28). One skilled in the art would recognize the advantage of having a needle mechanism that “automatically” entraps the tip of the needle when the shield is actuated. Wagner fails to provide this type of entrapment and the motivation for the incorporation would have been to enhance the shielding of the needle by the Wagner shield with an entrapment mechanism. This incorporation would also enhance the safety to the medical technician during the use of the device.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner in view of Kuracina. Wagner in view of Kuracina meets the claim limitations as described above but fails to include the latch having an arcuate surface being engageable with the needle.

However, it would have been an obvious matter of design choice by one skilled in the art to make the inside surface of the needle latch either at a right angle as shown in figures 30-31 of Kuracina or having a curved corner as claimed. Applicant has not disclosed that the latch having an arcuate surface solves a particular problem, is used for a particular purpose or provides an advantage. Furthermore, one would expect Kuracina's latch and applicant's arcuate surface latch to perform equally well given that both would perform the function of retaining the needle within the shield given that, in the prior art, it is the inside distal surface of the latch that prevents the needle tip from being accessed after use. The prior art latch performance would not be affected with either a curved latch or a latch having a right angle. Therefore, the modification would have been considered a mere obvious design choice that fails to patentably distinguish over the prior art.

Allowable Subject Matter

Claims 33,35,36 and 37 are allowed.

Response to Arguments

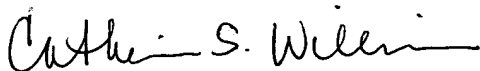
Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams
December 20, 2006

CATHERINE S. WILLIAMS
PRIMARY EXAMINER